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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,903	01/08/2007	Richard Head	024219-0105	3340
22428 7590 02/11/2011 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER YU, HONG				
ART UNIT		PAPER NUMBER		
1613				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,903

Applicant(s)

HEAD ET AL.

Examiner

HONG YU

Art Unit

1613

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-14 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/2010 has been entered.

Status of claims

The amendment filed on 12/15/2010 is acknowledged and have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claims 5-8 and 15-18 have previously been canceled, claims 1-4 and 9-14 have been withdrawn, and claims 19-25 have been added. Claims 19-25 are under examination in the instant office action.

Rejections withdrawn

Applicant's amendments have overcome the 102 rejection of claims 5, 7, 8, and 15-18 over Sair et al. (US 4,230,687) from the previous Office Action.

New ground of rejections necessitated by Applicant's amendment

New claims 19-25 necessitate the following new ground of rejections.

Claim Rejections - 35 USC § 112/Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 contains the trademark/trade names "Hylon", "Novelose", "Capsul", "Hi-Cap", and "Hi-Maize". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of **35 U.S.C. 112**, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe pre-processed resistant starch and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 20 and 22 introduces new matter as the claim recites the limitation "non-resistant starch". There is no verbatim recitation of "non-resistant starch" in the specification. The limitation of "non-resistant starch " was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses resistant starch but does not describe the instantly claimed limitation. There is no guidance in the specification to select "non-resistant starch" and the inclusion of "non-resistant starch" as an alternative of resistant starch broadening the scope of the claims. From MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor

had possession of the subject matter of the amendment at the time of filing of the instant application. Claim 21 is rejected as a dependent claim of a rejected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sair et al. (US 4,230,687) as evidenced by Wheat Flour (<http://en.wikipedia.org/wiki/Flour>).

Sair et al. meet all of the limitations of claims 19-21 and 23-25. Sair et al. disclose an encapsulation material forming protective matrix to encase vitamins (lipids) in order to prevent minimizing oxidation and controlling release of vitamins (lipids) comprising mixture of casein as a protein and Capsul as a pre-processed resistant starch (claim 1 and column 2, line 1 through column 9, line 24-28). Capsul is defined by Sair et al. as dextrin (example 25). Casein is defined as milk protein according to the disclosure in the instant specification (abstract). Sair et al. are silent about the active agents being storage unstable; however, Sair et al. disclose the active agents undergoing oxidation and flavor deterioration on storage which are understood as storage unstable. Sair et al. are silent about the encapsulation material releasing the therapeutic and nutritional agents in predetermined location in the gastro-intestinal tract.

The encapsulation material disclosed by Sair et al. comprises the same components as the encapsulation material recited in the instant claim, thus the encapsulation material disclosed by Sair et al. would necessarily possess the same release property as that of the encapsulation material recited in the instant claim.

Sair et al. meets all of the limitations of claim 21. Sair et al. discloses the starch being wheat flour (column 17, line 20-38). According to Wheat Flour wheat flour contains high proportion of starches (under Flour make up).

Response to applicants' 37 CFR 1.132 declaration:

The declaration under 37 CFR 1.132 filed on 12/15/2010 by Mary Ann Augustin is insufficient to overcome the rejection of claims 19-25 based upon Sair et al. because: the declaration filed by Mary Ann Augustin is opinion without factual support, thus is not persuasive. See *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("expert's opinion on the ultimate legal conclusion must be supported by something more than a conclusory statement"). MPEP 2164.05

Response to Applicants' arguments:

Applicant's arguments, filed on 10/15/2010, have been fully considered but they are moot in view of new ground of rejections. However the examiner would like to address the following arguments.

Applicants argue that according to the declaration filed by Mary Ann Augustin the encapsulating material disclosed by Sair et al. is not the same as the claimed encapsulating material.

However this argument is not deemed persuasive. As indicated in the 102 rejection above by the examiner, the encapsulating material disclosed by Sair et al. comprising mixture of casein as a protein and Capsul as a pre-processed resistant starch. Capsul is the claimed pre-processed resistant starch and casein is define as a milk protein according to the instant specification.

Applicants further argue that according to the declaration filed by Mary Ann Augustin the encapsulating material disclosed by Sair et al. is used to release active agents in mouth.

However this argument is not deemed persuasive. Chewing gum is one of the wide varieties of products disclosed by Sair et al. including vitamins (column 3, line 56-66) which are certainly not to be absorbed in mouth only.

Applicants argue again that according to the declaration filed by Mary Ann Augustin the encapsulating material disclosed by Sair et al. is heated above its melting point which is different form the procedure recited in the instant specification, thus affect the self-life and intended release site of the encapsulated agent.

However this argument is not deemed persuasive. Sair et al. disclose a method of making the encapsulating material by mechanically formed it into homogeneous gel

at relative low temperature, such as from below room temperature to near the boiling point of water (column 1, line 59 through column 2, line 51) which is as same as or below the temperature disclosed in the instant specification which is 98 °C (page 6, line 13-28 and page 8, line 14-24). Thus, the effect of the method of making the encapsulating material disclosed by Sair et al. would have the same effect on the self-life and intended release site of the encapsulated agent as claimed.

Respectfully, applicants' arguments are not persuasive. The predictable and expected result remains predictable and expected. Accordingly, the claims remain rejected for at least these reasons and the reasons of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on M-F 8:50 am-5:20 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brain-Yong Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./
Examiner, Art Unit 1613

/Ernst V Arnold/
Primary Examiner, Art Unit 1613